K120532

510(k) SUMMARY

MAY 2 2013

Getinge 633HC Steam Sterilizer Air Glide System

Submitted by:	Getinge Sourcing LLC 1777 E Henrietta Road Rochester, NY 14623-3133
Contact Person:	Barb Smith, RAC Sr. Manager, Regulatory Affairs Phone: (585) 214-6049 Fax: (585) 272-5299
Date prepared:	February 17, 2012
Proprietary Name:	Getinge 633HC Steam Sterilizer Air Glide System
Common Name:	Steam Sterilizer
Device Classification:	PEC Class II, as listed per 21 CFR 880.6880
Predicate Device:	K070657, Getinge 633HC Series Vacuum/Gravity Steam Sterilizer. S.E. Date 4/6/07

Description of Device:

The Getinge 633HC Steam Sterilizer Air Glide System is intended to provide automated loading and unloading of instruments requiring sterilization for increasing hospital work flow efficiencies. The Air Glide System is used with multiple Getinge Model 633HC 51" steam sterilizers with double-door, pass-through configurations. The system consists of a single point user interface station, loading conveyor, load transport shuttles, unloading conveyor and 2 to 7 Getinge Model 633HC Steam Sterilizers.

The 633HC AGS is designed to minimize the manual handling of sterilizer loads during transfer, chamber loading and chamber unloading of 633HC steam sterilizers. Users place the load car on the AGS conveyor, scan the load car with a barcode reader, scan the required cycle from the cycle list and click OK to enter the requirements into the AGS system. The AGS now automatically moves the load car to an available sterilizer and automatically loads the sterilizer, signals the sterilizer to run the required cycle and following a successful cycle will automatically unload the sterilizer on the unload end and move the load to the unload conveyor for pick up. Users do not need to load and unload individual sterilizers. The 633HC sterilizer controls the sterilization cycle as it normally would and does not open the unload door unless the cycle completed without error.

Intended Use:

The Getinge 633HC Steam Sterilizer Air Glide System is intended to provide automated loading and unloading of instruments requiring sterilization for increasing hospital work flow efficiencies. The Air Glide System is used with multiple Getinge Model 633HC 51" steam sterilizers with double-door, pass-through configurations. The system consists of a single point user interface station, loading conveyor, load transport shuttles; unloading conveyor and 2 to 7 Getinge Model 633HC Steam Sterilizers.

The intended use of the 633HC Steam Sterilizer has not changed; Intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

Comparisons to Predicate Device:

Similarities between the Getinge 633HC Steam Sterilizer Air Glide System and the identified predicate are:

- Intended use of the 633HC Steam Sterilizer is the same: Intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.
- Operating Principle of the 633HC Steam Sterilizer is the same: Saturated steam is the sterilizing agent.
- There is no direct patient contact associated with this device.
- Cycle Types: The cycle types offered on the 633HC Steam Sterilizer are the same.
- The interior of the 633HC Steam Sterilizer and the loading car that goes into the sterilizer are the same.

The differences between the Getinge 633HC Steam Sterilizer Air Glide System and the predicate device (Getinge 633HC Series Vacuum/Gravity Steam Sterilizer) are:

- The only change made to the 633HC sterilizer to accommodate the AGS is a software change to allow the AGS to automatically open the door, close door, start a cycle and automatically open the unload door when the cycle is properly completed and the addition of a NetCOM card to allow communication with the AGS.
- The 633HC AGS allows for automated loading and unloading of a bank of double-door pass-through Getinge Model 633HC 51" steam sterilizers. Users do not need to load and unload individual sterilizers.

- The main application of the 633HC AGS is in the high volume, large sterile reprocessing centers of large hospitals or offsite reprocessing centers supplying sterile goods to multiple hospitals.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The Getinge 633HC Steam Sterilizer Air Glide System is a substantially equivalent device to that of the predicate device. There have been no substantial changes in the sterilization technology and no changes to the intended use of this device (sterilization of hospital goods). Based on the information provided, it is our opinion that the Getinge 633HC Steam Sterilizer Air Glide System is substantially equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

Ms. Barb Smith
Senior Manager, Regulatory Affairs
Getinge Sourcing LLC
1777 East Henrietta Road
ROCHESTER New York 14623-3133

Re: K120532
Trade/Device Name: Getinge 633HC Steam Sterilization Air Glide System
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: PEC
Dated: February 17, 2012
Received: April 30, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson -S 2013.05.02 16:00:49 -04'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Getinge 633HC Steam Sterilizer Air Glide System

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie

Digitally signed by Elizabeth F. Claverie
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000558644, cn=Elizabeth F. Claverie
Date: 2013.05.02 15:13:38 -04'00'

Division Sign-Off)
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